JUL 17 2003 K031467

# 510(k) Summary
# Shofu Dental Corporation
# Glasionomer FX-II

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| **Submitted by:** | Robert Noble, President<br>Shofu Dental Corporation<br>1225 Stone Drive<br>San Marcos, CA 92069-4059<br>(760)736-3277<br>FAX: (760)736-3276 |
| **Company Contact:** | Robert Noble, President |
| **Date Summary Prepared** | May 2, 2003 |
| **Trade Name** | Glasionomer FX-II |
| **Common Name** | Dental Cement |
| **Classification** | EMA |
| **Product Code** | 872.3275(b) |
| **Substantially Equivalent Devices** | Fuji GP [510(k) Number – K961448]<br>Hy Bond Glasionomer CX [510(k) Number – K940122] |

## Description of Glasionomer FX-II

Glasionomer FX-II is a glass polyalkenoate cement used for dental restorations, for Minimal Intervention (MI) dentistry.

## Intended Use:

Glasionomer FX-II is a glass polyalkenoate cement used for dental restorations. Glasionomer FX-II is intended for use as a final restorative for deciduous teeth; a geriatric restorative for Class I, II, III and V cavities and cervical erosions; a final restorative for Class I and II of adult dentition in non-load bearing situations; an intermediate restorative for heavy stress cavities; a core build up; and for pit and fissure fillings.

**Components:**

Glasionomer FX-II is available in two (2) different sets:

The 1-1 Set contains the following and is available in four (4) shades: A2, A3, A3.5 and B2:

- Powder 15g
- Liquid 8ml (10g)
- Spatula
- Cocoa Butter 1g
- Mixing Pad
- Matrix Strips
- Powder Scoop
- Instructions for Use

The Mini Set contains the following and is available in the same four (4) shades: A2, A3, A3.5 and B2:

- Powder 6g
- Liquid 2.8ml (3.5g)
- Powder Scoop
- Instructions for Use

Refills are available: single powder (15g) for all four (4) shades and a single liquid (8ml).

## Biocompatibility

Glasionomer FX-II **passed** the following biocompatibility tests:

- Acute oral toxicity
- Bacterial reverse mutation
- *In vitro* cytotoxicity
- Subcutaneous implantation
- Sensitization

## Conclusion

The Glasionomer FX-II is substantially equivalent to Fuji GP powder 510(k) K961448 and Hy-Bond Glasionomer CX liquid 510(k) K940122.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. Robert Noble
President
Shofu Dental Corporation
1225 Stone Drive
San Marcos, California 92069-4059

Re: K031467
Trade/Device Name: GlasIonomer FX-II
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA
Dated: May 02, 2003
Received: May 20, 2003

Dear Mr. Noble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

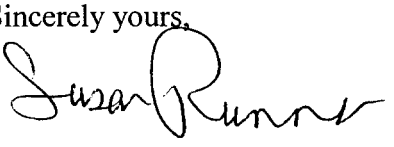
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K031467

**Device Name:** Glasionomer FX-II

**Indications For Use:**

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**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Kevin Mulry for KSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031467

(Optional Format (3-10-98)